

b.) Remarks

Claim 2 has been amended, and claims 30 and 31 presented, to better recite the patentable nature of the present invention. Claims 5, 12 and 16 are amended to maintain their dependency. Support for the amendment can be found in the specification as filed, *inter alia*, at page 11, lines 5-11. Accordingly, no new matter has been added.

Claims 7, 12 and 16-17 are withdrawn from consideration. Rejoinder of claims 7 and 12 is respectfully requested upon allowance of an antecedent claim.

Claims 1-6 and 24-27 are rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility and under 35 U.S.C. §112, first paragraph, as failing to enable one skilled in the art to make and/or use the invention.

In support of these rejections, the Examiner states there is no evidence the current nucleic acid or protein are induced in cells upon infection with Epstein-Barr virus. In this regard, the Examiner discounts the partial 99.3% homology of EBI-3-alt to EBI-3 since there is no reason to think the current protein is activated by Epstein-Barr virus or would serve as a marker.

Applicants respectfully traverse this rejection. Although EBI-3 was originally identified in Epstein-Barr virus-infected B lymphocytes, it is the protein's recently identified function as a novel heterodimeric hematopoietin which makes it particularly useful as an immunomodulator (see Devergne et al., Proc. Natl. Acad. Sci. USA 94:12041-12046 (1997), of record).

Regardless of whether the current protein is also induced by Epstein-Barr

virus, those of skill in the art plainly recognize that, based on the strong homology between the two proteins, EBI-3-alt is also exceedingly likely to function as important component of the immune system.<sup>1/</sup> This is clearly supported by the fact that both proteins contain the receptor\_cytokine\_1 signature sequence C-[LVFYR]-x(7,8)-[STIVDN]-C-x-W (see page 6, lines 25-39, and SEQ ID NO: 5). Thus, according to Example 10 of the Utility Guidelines, the current protein (and the nucleic acids which encode it) has a specific, substantial, and credible utility based on its similarity to a known protein with immunomodulatory activity.<sup>2/</sup>

This is all the Patent Statute requires.

Claims 1, 3-6, 26 and 27 are rejected under 35 U.S.C. § 112, first paragraph, as reciting subject matter which was not adequately described in the specification at the time the application was filed. Although this rejection is respectfully traversed, solely in order to expedite prosecution, claim 1 has been cancelled.

Claims 1, 3-6, 26 and 27 are rejected under 35 U.S.C. §102(b) as being anticipated by Birkenbach (U.S. Patent No. 5,744,301). This rejection too is respectfully traversed, but is mooted by Applicants' cancellation of claim 1, also solely in order to expedite prosecution herein.

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<sup>1/</sup> The Examiner notes that EBI-3-alt also has some homology (50% over residues 5-32) to a nitrous oxide reductase catalytic subunit from *Pseudomonas fluorescens*. This homology to two disparate proteins, the examiner believes, highlights the absence of any substantial utility for EBI-3-alt. The protein in Example 10 of the Utility Guidelines (which was 95% homologous to DNA ligase), however, also had 50% homology to an unrelated alpha-actin. Nevertheless, it was concluded that, based on the strong homology to DNA ligase, a utility rejection should not be made.

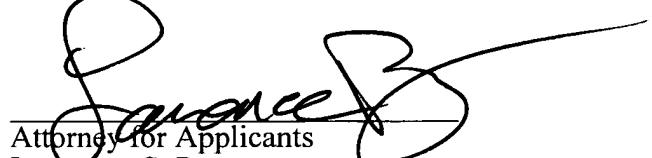
<sup>2/</sup> The Examiner contends that the current situation is more analogous to Example 12 of the Utility Guidelines, rather than Example 10. Example 12, however, describes a putative receptor of unknown function which binds to a protein, also of unknown function. In contrast, the current protein has strong sequence and structural homology to a known protein with use as an immunomodulator.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 2, 5-7, 12 and 16-17 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

  
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